4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0359]

National Medical Device Postmarket Surveillance System Planning Board Report; Availability, Web Site Location and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report and Web site location where the Agency has posted the report entitled "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," developed by the National Medical Device Postmarket Surveillance System Planning Board. In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on this document to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Thomas P. Gross, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2316, Silver Spring, MD 20993-0002, 301-796-5700, email: Thomas.Gross@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's Center for Devices and Radiological Health is responsible for protecting the public health by assuring the safety and effectiveness of medical devices. A key part of this mission is to monitor medical devices for continued safety and effectiveness after they are in use and to help the public get the accurate, science-based information they need to improve their health.

In September 2012, the FDA published a report, "Strengthening Our National System for Medical Device Postmarket Surveillance," that proposed a strategy for improving the current system for monitoring medical device safety and effectiveness. In April 2013, the FDA issued an update to the September 2012 report that incorporated public input received and described the next steps towards fulfilling the vision for building a national postmarket surveillance system. These reports can be found at FDA's Web site http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm.

One of these next steps consisted of establishing a multistakeholder planning board to identify the governance structure, practices, policies, procedures, methodological approaches, and business model(s) necessary to facilitate the creation of a sustainable, integrated medical device postmarket surveillance system that leverages and complements existing and ongoing efforts. Under a cooperative agreement with the FDA, the Engelberg Center for Health Care Reform at the Brookings Institution convened the National Medical Device Postmarket Surveillance Planning Board (the Planning Board) in 2014. The Planning Board membership included representatives from a broad array of stakeholder groups and areas of expertise

including patients, provider organizations, hospitals, health plans, industry, and government agencies, as well as methodologists and academic researchers.

The Planning Board was tasked with developing a set of long-term principles and priorities for a National Postmarket Surveillance System. The task included identifying potential governance and business models that address legal and privacy considerations, system financing and stability, mechanisms to support the appropriate use of data, and policies to ensure system transparency. The Planning Board was also asked to provide recommendations about how to leverage the system to meet the needs of other medical device stakeholders and groups seeking to develop better evidence (http://www.brookings.edu/about/centers/health/call-for-nominations and https://dcri.org/events/past-meetings/MDEpiNet-nominations).

This notice announces the availability and Web site location of the Planning Board's report entitled "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System." FDA invites interested persons to submit comments on this report. We have established a docket where comments may be submitted (see ADDRESSES). We believe this docket is an important tool for receiving feedback on this report from interested parties and for sharing this information with the public. The report "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System" can be found at FDA's Web site http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: February 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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